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Michael Huenerbein

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EXAMINER

TOWA, RENE T

ART UNIT

PAPER NUMBER

3736

NOTIFICATION DATE

DELIVERY MODE

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ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No. 10/538,649	Applicant(s) HUENERBEIN, MICHAEL	
	Examiner RENE TOWA	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-8 and 10-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-8 and 10-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office action is responsive to an amendment filed January 22, 2008. Claims 2-8 & 10-15 are pending. Claims 2, 4-8, 10-11 & 13 have been amended. Claims 1 & 9 have been cancelled. New claims 14-15 have been added.

Claim Objections

2. Claims 10-12 are objected to because of the following informalities:

In regards to claims 10-11, at step (c), the term "seperating" should apparently read --separating--.

In regards to claim 12, at line 1, the claim refers to a cancelled claim (i.e. claim 1) and should apparently refer to claim 13.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The rejection is withdrawn due to amendments.

Claim Rejections - 35 USC § 101

4. The rejection is withdrawn due to amendments.

Claim Rejections - 35 USC § 102

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. **Claims 2, 6, 8, 10 & 13** are rejected under 35 U.S.C. 102(b) as being anticipated by Boebel (US 4,620,547).

In regards to **claim 13**, Boebel discloses an optical biopsy instrument comprising:

(a) a substantially cylindrical cannula 1 with a proximal end and a distal end, said cannula 1 having at least one lateral opening 2 in a side surface of the cannula 1, and

(b) an endoscope (5, 6, 7) which is axially movable inside the cannula 1 wherein a clearance formed between the cannula 1 and the endoscope (5, 6, 7) is selected such that a separation of a tissue sample from a tissue is enabled by direct interaction of the endoscope (5, 6, 7) with the at least one lateral opening 2 by moving at least one of the cannula 1 and the endoscope (5, 6, 7) relative to each other (see figs. 1-3; col. 1, lines 7-15; col. 2, lines 18-34, 38-43 & 50-66).

In regards to **claim 2**, Boebel discloses an optical biopsy instrument characterized in that the at least one lateral opening 2 of the cannula 1 has at least in parts a cutting region 3 at its area being directed towards the distal end (see fig. 2; col. 2, lines 18-34).

In regards to **claim 6**, Boebel discloses an optical biopsy instrument characterized in that an external diameter of the endoscope (5, 6, 7) (i.e. the diameter of cutter 6 of endoscope (5, 6, 7)) substantially corresponds to an internal diameter of the cannula 1 (see fig. 2).

In regards to **claim 8**, Boebel discloses an optical instrument characterized in that the endoscope (5, 6, 7) is a rigid endoscope (5, 6, 7) (see fig. 2).

In regards to **claim 10**, Boebel discloses a method for sampling a tissue sample in duct systems (i.e. the uterus) comprising the steps of:

(a) introducing an optical biopsy instrument, under endoscopic monitoring, into a duct up to a biopsy site, said optical biopsy instrument comprising

-a substantially cylindrical cannula 1 with a proximal end and a distal end, said cannula 1 having at least one lateral opening 2 in a side surface of said cannula 1, and

-an endoscope (5, 6, 7) which is axially movable inside the cannula 1, wherein a clearance formed between the cannula 1 and the endoscope (5, 6, 7) is selected such that a separation of a tissue sample from a tissue is enabled by direct interaction of the endoscope (5, 6, 7) with the at least one lateral opening 2 by moving at least one of the cannula 1 and the endoscope (5, 6, 7) relative to each other,

(b) bringing the tissue sample through the at least one lateral opening 2 into the interior of the cannula 1, and

(c) separating the tissue sample from the rest of the tissue by retracting the endoscope (5, 6, 7) until the at least one lateral opening 2 is closed (see figs. 1-3; col. 1, lines 7-15 & 39-46; col. 2, lines 18-34, 38-43 & 50-68; col. 3, lines 1-6).

Claim Rejections - 35 USC § 103

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. **Claim 3** is rejected under 35 U.S.C. 103(a) as being unpatentable over Boebel ('547) in view of Hayafuji et al. (US 5,106,364).

Boebel discloses an optical instrument, as described above, that fails to explicitly teach a cutting region formed by a ground.

However, **Hayafuji et al.** disclose a biopsy instrument comprising at least one substantially rectangular lateral opening 18; wherein the at least one lateral opening 18 includes a cutting region 41 formed by a ground edge of the at least one lateral opening 18 (see figs. 2-4; col. 5, lines 20-29 & 51-64; col. 6, lines 18-34 & 51-62).

Since both Boebel and Hayafuji et al. teach biopsy devices for cutting tissue wherein a cutting edge of a moveable endoscope or plunger cooperates with a mating cutting edge of a lateral opening in a scissor-like action (see abstracts), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the instrument of Boebel with a ground edge cutting region as taught by Hayafuji et al. in order to cut tissue such that a cutting edge of a moveable endoscope or plunger cooperates with a mating cutting edge of a lateral opening in a scissor-like action.

9. **Claim 4** is rejected under 35 U.S.C. 103(a) as being unpatentable over Boebel ('547) in view of Lifton ('753).

Boebel discloses an optical instrument, as described above, that fails to explicitly teach that the at least lateral opening that is round, oval, elliptic or rectangular in configuration.

However, **Lifton** discloses a biopsy instrument characterized in that the at least one lateral opening has a substantially oval or elliptic configuration (see fig. 2; col. 3, lines 18-23).

Since both Boebel and Lifton disclose biopsy instruments comprising lateral

opening on a side surface thereof to collect severed biopsy samples into a cavity of the instrument, it would have been obvious to one ordinary skill in the art at the time Applicant's invention was made to provide the instrument of Boebel with an oval lateral opening as taught by Lifton since such a modification would amount to an obvious design choice that would serve the same purpose of collecting severed biopsy samples into a cavity of the instrument.

10. **Claim 5** is rejected under 35 U.S.C. 103(a) as being unpatentable over Boebel ('547) in view of Yoon (US 4,254,762).

Boebel discloses an optical instrument, as described above, that fails to explicitly teach a transparent distal end wall.

However, **Yoon** discloses an optical biopsy instrument comprising a transparent distal end wall for forward viewing (see fig. 7; col. 3, lines 58-65; col. 5, lines 41-46; col. 6, lines 43-49 & 55-58).

Since both Boebel and Yoon teach optical biopsy instruments comprising optical system for viewing the tissue region to be biopsied, it would have been obvious to one ordinary skill in the art at the time Applicant's invention was made to provide the instrument of Boebel with a transparent end wall as taught by Yoon in order to observe the tissue region to be biopsied via either one of forward or lateral viewing.

11. **Claims 7 & 14-15** are rejected under 35 U.S.C. 103(a) as being unpatentable over Boebel ('547) in view of Gatto (US 2003/0181823).

Boebel discloses an optical instrument, as described above, that fails to explicitly

teach a cannula diameter of at most 1.2 mm.

However, **Gatto** discloses an optical biopsy instrument (see figure 1), characterized in that an external diameter of the cannula is 1.2 mm at most for traversing a mammary gland milk duct (see par 0018 & 0035-0036).

Since both Boebel and Gatto disclose optical biopsy instruments for use in duct systems, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the instrument of Boebel with a cannula external diameter of at most 1.2 mm as taught by Gatto in order to provide the instrument with the ability to traverse the narrow diameter of the breast ducts (see Gatto, par 0009 & 0018).

12. **Claim 11** is rejected under 35 U.S.C. 103(a) as being unpatentable over Boebel ('547) in view of Wang (US 4,702,260).

Boebel discloses a method for sampling a tissue sample in duct systems (i.e. the uterus) comprising the steps of:

(a) introducing an optical biopsy instrument, under endoscopic monitoring, into a duct up to a biopsy site, said optical biopsy instrument comprising

-a substantially cylindrical cannula 1 with a proximal end and a distal end, said cannula 1 having at least one lateral opening 2 in a side surface of said cannula 1, and

-an endoscope (5, 6, 7) which is axially movable inside the cannula 1, wherein a clearance formed between the cannula 1 and the endoscope (5, 6, 7) is selected such that a separation of a tissue sample from a tissue is enabled by direct

interaction of the endoscope (5, 6, 7) with the at least one lateral opening 2 by moving at least one of the cannula 1 and the endoscope (5, 6, 7) relative to each other,

(b) bringing the tissue sample through the at least one lateral opening 2 into the interior of the cannula 1, and

(c) separating the tissue sample from the rest of the tissue by retracting the endoscope (5, 6, 7) until the at least one lateral opening 2 is closed (see figs. 1-3; col. 1, lines 7-15 & 39-46; col. 2, lines 18-34, 38-43 & 50-68; col. 3, lines 1-6).

Boebel discloses a method wherein the tissue is separated by moving the endoscope relative to the cannula, as described above, but fails to explicitly teach that the tissue could also be separated by moving the cannula instead, together with a fixed endoscope forward or backward.

However, **Wang** discloses a biopsy method wherein the tissue is separated by moving a cannula together with a fixed inner cutting element forward or backward to sever tissue (see figs. 2 & 4; col. 4, lines 18-40).

Since Boebel and Wang teach biopsy instruments wherein the outer cannula is capable of separating tissue moving a cannula together with a fixed inner cutting element forward or backward to sever tissue, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the method of Boebel with a step of separating the tissue by moving the cannula as taught by Wang in order to sever the tissue.

13. **Claim 12** is rejected under 35 U.S.C. 103(a) as being unpatentable over Boebel ('547) in view of Berman et al. (US 6,217,598).

Boebel discloses a method, as described above in claim 13, that fails to explicitly teach a lateral opening with cutting teeth.

However, **Berman et al.** disclose a biopsy instrument comprising an outer cannula comprising a lateral opening with cutting teeth (218, 220) (see fig. 22; col. 6, lines 64-67; col. 7, lines 1-18).

Since both Boebel and Berman et al. teach biopsy devices comprising outer and inner cutting members, it would have been obvious to one ordinary skill in the art at the time Applicant's invention was made to provide the instrument of Boebel with cutting teeth as taught by Berman et al. in order facilitate tissue cutting by spreading a cut from multiple points of initial puncture (i.e. via the teeth).

Response to Arguments

14. Applicant's arguments filed January 22, 2008 have been fully considered but they are not persuasive. Applicant argues that Boebel fails to teach to teach a clearance formed between a cannula and an endoscope selected to enable tissue sample separation by direct interaction of a lateral opening with the endoscope. This argument has been considered but has not been deemed persuasive.

In regards to the Applicant's argument, the Examiner respectfully traverses. The Examiner notes that Boebel does teach an endoscope that the Examiner had previously indicated to be numeral 5 contrary to the Applicant's reference to numeral 7. Indeed, Boebel teaches a device that comprises an inner shaft 5 having an integrally formed extension or ring of a larger diameter acting as a cutter 6 (see col. 2, lines 29-37). The inner shaft 5 further includes an optical system 7 coupled therewith, which optical

system further comprises a lateral objective (see col. 2, lines 18-25, 38-43 & 51-56). It is thus apparent that the inner shaft 5, cutter 6, and optical system 7 integrally form the "endoscope." As such, the Examiner submits that Boebel fully teaches an endoscope. Moreover, Boebel teaches a clearance formed between the outer shaft 1 and the cutter 6 of the endoscope selected to enable tissue sample separation by direct interaction of the lateral opening 2 with the endoscope (i.e. the cutter 6 has a cutting edge 4 that cooperates with a mating cutting edge 3 of an outer shaft 1) (see col. 2, lines 18-23 and figure 2).

In view of the foregoing, the rejections over Boebel are maintained.

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to RENE TOWA whose telephone number is (571)272-8758. The examiner can normally be reached on M-F, 8:00-16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. T./
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736